

REMARKS

Claims 1-25 are pending in the application. Claim 1 is the only independent claim.

Claims 1-25 were rejected under 35 USC 103(a) as being unpatentable over US Patent 5,799,661 (Boyd et al.) in view of US Patent 5,837,003 (Ginsburg). This rejection is traversed and reconsideration is requested.

Independent Claim 1 is directed to a coronary bypass procedure comprising positioning a heat transfer element in a blood vessel of a patient, cooling the body of the patient to less than 35°C using said heat transfer element and forming a fluid communicating graft between an arterial blood supply and the coronary artery. The patient's blood is oxygenated with the patient's lungs and blood is circulated using the patient's heart or using an intracorporeal pump.

The Action takes the position that Boyd discloses "a coronary bypass procedure comprising the steps of cooling the body of the patient to less than 35°C using a heat transfer element" and "forming a fluid communicating graft between the blood supply and the coronary artery and the patient's blood is oxygenated in the patient's lungs by the patient's heart or intracorporeal pump".

The Action acknowledges that the heat exchanger of Boyd is a "topical device" and takes the position that it would have been obvious to one of ordinary skill in the art "to control the body temperature of a patient undergoing coronary bypass procedure by using a heat exchanger designed for insertion into the blood vessel of the patient as taught by Ginsburg, instead of the topical exchanger thereby avoiding the problems of thermal shock to the myocardial tissues".

First, Applicants respectfully submit that Boyd does *not* teach or suggest a coronary bypass procedure comprising the steps of "cooling *the body of a patient* to less than 35 degrees C using a heat transfer element". Boyd describes only applying "topical hypothermia *to the heart* to reduce oxygen demand by the myocardium" (col. 4, lines 63-67). Boyd is directed to coronary artery bypass graft surgery 'through port-access or closed-chest thoracoscopic methods', and provides absolutely no teaching or suggestion of cooling the body of a patient, but only to "cooling the *heart* during the multi-vessel CABG procedure" (col. 2, lines 58-60).

Applicants further respectfully submit that one skilled in the art would *not* be motivated, based upon the teachings of Boyd and Ginsburg, to combine the teachings therein in the manner proposed in the Action. Again, Boyd is directed to a method/device “for port-access multivessel coronary artery bypass surgery” (i.e., through small incisions made through the intercostal spaces between the patient’s ribs”). Boyd describes only a “port-access topical cooling device for improving myocardial protection during the port-access procedure” (Abst). More specifically, at cols. 21-22 and Figs. 42-45, Boyd describes the “hypothermia device 230” that is inserted “through an access port into the chest of the patient” – the “distal end of an introducer sheath 231 is placed under the heart H and then withdrawn...thereby placing the flexible heat exchanger 231 under the heart H” (col. 21, lines 55-58). Boyd specifically describes that the “flexible heat exchanger 231 is constructed so that it curves to conform to the exterior of the heart H when inflated to the deployed position,...to create a better thermal contact with the myocardium...to rapidly cool the heart”.

Applicants’ note the Examiner’s comment in the Office Action that it would have been obvious...“to control the body temperature of a patient undergoing coronary bypass procedure by using a heat exchanger designed for insertion into the blood vessel of the patient as taught by Ginsburg, instead of the topical exchanger (taught by Boyd) thereby avoiding the problems of thermal shock to the myocardial tissues” -- however, Boyd clearly recognized the desire to “prevent thermal shock to the myocardial tissue” (col. 22, lines 10-11), but to do so, in the recited “alternate embodiment”, Boyd *only* teaches (1) that the “flexible heat exchanger 231 may be covered with a thermal insulating material”, and (2) “to use a more moderate temperature for the cooling fluid, with better thermal contact and a higher flow rate to rapidly cool the myocardium without the risk of thermal shock” (col. 22, lines 8-15).

Boyd simply provides absolutely no teaching or suggestion to “cool the entire body of the patient to less than 35°C using a heat transfer element”. Boyd’s “topical cooling device” is clearly designed and intended to “conform to the exterior of the heart...to create a thermal contact with the myocardium” to “rapidly cool the heart” (col. 22, lines 1-7).

The combination/modification proposed in the Office Action, allegedly based on the teachings of Boyd and Ginsburg, clearly fails to meet the requirement that there be "some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995). Of course, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.". The requisite motivation must come from the prior art and not Applicants' specification. When an invention is directed to a combination of elements, both the Federal Circuit and the Board have consistently reversed rejections found on references merely showing that the claimed elements or subcombinations of the claimed elements were known.

The references must expressly or impliedly suggest the claimed combination or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Here, one skilled in the art would *not* be motivated, at least based on the teachings of Boyd and Ginsburg, to combine the teachings in the manner suggested.

Therefore, since there is no factual basis in the record for the making the Examiner's proposed combination, it is respectfully submitted that there is no *prima facie* case of obviousness and the rejection must be withdrawn.

For all of the foregoing reasons, independent Claim 1 is believed to be clearly patentable over Boyd and Ginsburg and reconsideration is respectfully requested.

Dependent Claims 2-25 are believed to be clearly patentable for all of the reasons indicated above with respect to Claim 1 from which they depend, and even further distinguish over the cited references by reciting additional limitations. For example, dependent Claim 10 recites that the patient's circulation is supported with a pump positioned in the patient's vasculature, and that the pump is at least partially positioned in the left ventricle and is introduced through the femoral artery. The Office Action cites "column 4 of Ginsburg" as providing such a teaching. However, Applicants note that Ginsburg merely notes that the "*intravascular catheter* will be inserted into a blood vessel, usually being the femoral artery...". There is absolutely no teaching or suggestion in Boyd or Ginsburg to introduce a pump "through the femoral artery".

In addition, with respect to the structural recitations included in Claims 20-22, including “the heat transfer element comprising a plurality of exterior surface irregularities being shaped and arranged to create mixing in the blood”; and “a plurality of interior surface irregularities within the heat transfer element being shaped and arranged to create mixing in fluid within the heat transfer element”, and “the interior and exterior surface irregularities comprising one or more helical ridges and one or more helical grooves” (respectively), the Office Action directs Applicants to Figures 5 and 11 of Ginsburg. Again, Applicants respectfully submit that it would not be obvious to modify/combine the teachings of Ginsburg with Boyd, when Boyd clearly teaches only the use of “topical cooling of the heart”. In addition, Figure 11 of Ginsburg illustrates only a “wire coil resistance heater” 106 surrounding surface 108. There is no teaching or suggestion of a “plurality of *interior surface irregularities* within the heat transfer element being shaped and arranged to create mixing in fluid within the heat transfer element”.

Since the Applicant has fully responded to the rejection set out in the Office Action, it is respectfully submitted that in regard to the above amendment and remarks that the pending application is patentable over the art of record and prompt review and issuance is accordingly requested. Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, request is made that the Examiner telephone the Applicant’s undersigned attorney at (908) 518-7700 in order that any outstanding issues may be resolved.

Respectfully submitted,



Karin L. Williams Registration No 36,721

Certificate of Mail

I hereby certify that this document and any document referenced herein is being deposited with the US Postal Service as first class mail under 37 C.F.R. 1.8 and addressed to Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on October 2, 2003

Karin L. Williams, Reg. No. 36,721

(Printed Name of Person Mailing Correspondence)

  
(Signature)

Patent  
10/008,999

**Please Continue to Send All Correspondence to:**

Mark D. Wieczorek  
Innercool Therapies, Inc.  
3931 Sorrento Valley Blvd.  
San Diego CA 92121

